

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

I. Status of the claims

Claims 6 and 13 were previously cancelled. Claims 9-11, 23, 29 and 44-46 are withdrawn as non-elected subject matter. Upon the identification of allowable subject matter in the elected composition claims, Applicants will amend the withdrawn method claims to recite the limitations of the allowed claims, and request rejoinder and examination of the withdrawn claims.

Claim 29 is amended to correct obvious typographical errors in the recitation of chemical names. Claims 1 and 47 are amended to replace “from greater than 30% to about 92%” with “from 33% to about 92%” This amendment is supported by original claim 5, which recited “from about 30% to about 92%,” and the specification at paragraph [0030], which defines “about” as follows:

As used herein, “about” will be understood by persons of ordinary skill in the art and will vary to some extent on the context in which it is used. If there are uses of the term which are not clear to persons of ordinary skill in the art given the context in which it is used, “about” will mean up to plus or minus 10% of the particular term.

Accordingly, the term “about 30” equates to $30 \pm 10\%$, *i.e.*, from 27 to 33. Accordingly, the specification supports each of 27, 30 and 33%. No new matter is added.

It is acknowledged that the foregoing amendments are submitted after final rejection of the claims. However, because the amendments do not introduce new matter, and either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested. The foregoing amendments to the claims are made solely to advance prosecution and not in acquiescence to any rejection, without prejudice to, or disclaimer of, any subject matter removed by amendment. Applicants reserve

the right to pursue any subject matter removed by amendment in continuing applications with the same right of priority as the present application.

Following the foregoing amendments, claims 1-5, 7-12 and 14-47 are pending and claims 1-5, 7, 8, 12, 14-22, 24-28, 30-43 and 47 are under examination.

II. Rejections under 35 U.S.C. § 112, first paragraph, written description

At page 2 of the Office Action claims 1-4, 7, 8, 12, 14-22, 24-28, 30-43 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. It is alleged that the specification's recitation of "from about 30% to about 92%" does not support "greater than 30% to about 92%." Applicants respectfully traverse, as support *in haec verba* is not required. *See* MPEP § 2163. Nevertheless, solely to advance prosecution, Applicants have amended claims 1 and 47 to recite "from 33% to about 92%." This amendment is fully supported by, *e.g.*, original claim 5 and the specification at paragraph [0030] and therefore overcomes the written description rejection. Moreover, claims 2-4, 7, 8, 12, 14-22, 24-28 and 30-43, which depend from claim 1, are believed to comply with the written description requirement because of the amendment to claim 1. Accordingly, all claims comply with the written description requirement. Reconsideration and withdrawal of the rejection is respectfully sought.

III. Rejections under 35 U.S.C. § 112, first paragraph, enablement

At pages 2-4 of the Office Action, claims 1-5, 7, 8, 12, 14-22, 24-28, 30-43 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action reasons (at page 3) that the claimed composition is inoperable because U.S. Patent No. 4,882,157 to Yang ("Yang") allegedly teaches at col. 6, lines 60-68, that if there is more than 30% water, the compositions are inoperable because of microorganism growth. Applicants respectfully traverse the rejection as it would have been applied to the presently pending claims, for each of the following reasons.

A. The Examiner is applying the incorrect legal standard for enablement.

The Examiner is requiring the applicant's invention to overcome a problem in the prior art. The claims are rejected for a lack of enablement because the prior art (Yang) indicates that microorganism growth is a problem when the water content is about 30%. This is not the standard to determine whether the applicant's claims are enabled by the specification. The enablement requirement under 35 U.S.C. § 112, first paragraph, requires that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. MPEP § 2164 (Emphasis Added). The information contained in specification must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. (Emphasis Added)

Claims are presumed enabled. And the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (emphasis added) (examiner must provide a reasonable explanation as to why the scope of protection provided by the claimed invention is not adequately enabled by the disclosure). Thus, the proper analysis to question whether the claims are enabled is to identify the scope of the claims, and then look to the specification to see whether it teaches one of ordinary skill in the art to make and use the invention.

First, considering the claim scope, the claims do not recite any aspect of microorganism growth. In fact, the Examiner recognizes that the claimed invention is not directed to the problem of minimizing microorganism growth. See page 4, 4th paragraph. It would therefore be incorrect for the Examiner to require the claims to be enabled against microorganism growth when the claims are silent regarding microorganism growth.

Second, the Office is asserting that the claimed compositions are not enabled, even though these compositions are *actually reduced to practice*. Examples 1-5 describe the manufacture and testing of compositions. Examples 6 and 7 show *in vivo* testing in beagles of a composition with a 90% water content, well above the 33% minimum of the present claims and the 30% from which Yang teaches away. Thus, the specification shows not only

how to make, and how to use, but actually makes and uses the claimed compositions.

Accordingly, one skilled in the art is enabled by the specification to make and use the invention,

Third, if the Examiner's test for enablement were followed to its natural conclusion, the Examiner should also require the applicant's invention to overcome the loss of chewiness in a dosage form containing a moisture content above 30%. This is because Yang also identifies loss of chewiness as a problem. Yang at col. 6, lines 60-68, literally states that:

the balance of the moisture content, [] must be maintained within the range of about 1 to about 30% by weight. Outside these ranges, the delivery system fails to be operable. Too low a moisture content results in a brittle and crumbly product which is neither palatable or effective in masking activities. At higher limits of moisture, microorganism growth becomes a problem and the texture loses its chewiness.

The present claims do not require any chewiness of the dosage form and the specification does not talk about the chewiness of the dosage form. The claims, however, should not be rejected as not enabling for chewiness. Rather, the applicant makes this point to identify the error in the Examiner's test for enablement. The test for enablement is not whether the claimed invention overcomes the problems of the prior art. Rather, the test is whether the specification is sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.

Using the correct test for enablement as set forth in MPEP § 2164, Applicants have:

(a) enabled the invention as presently claimed, and (b) demonstrated this enablement by actual reduction to practice. To the extent that Yang teaches away, this is irrelevant to the analysis whether the present claims are enabled n. For each, and all, of these reasons, the claims are enabled. Reconsideration and withdrawal is respectfully sought.

CONCLUSION

Applicants believe that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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